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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,689	08/19/2002	Fredericus Bernardus Josephus Maria Thummissen	13189-PCT-US	3731

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EXAMINER

CALAMITA, HEATHER

ART UNIT PAPER NUMBER

1637

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34-

Office Action Summary

Application No.

10/069,689

Applicant(s)

THUNNISSEN ET AL.

Examiner

Heather G. Calamita, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-9, 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5 and 10, drawn to a method for detecting a nucleotide sequence, classified in 435, subclass 287.2.
 - II. Claims 6-8 and 11-14, drawn to a device/kit for detecting a nucleotide sequence, classified in class 435, subclass 810.
 - III. Claim 9, drawn to a method of organizing microarray analysis classified in class 435, subclass 287.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I and II) and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method for detecting a nucleotide sequence can also be used to detect proteins.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention II is drawn to a kit utilized for detecting the presence or absence of a nucleotide sequence.

Invention III is drawn to a method of organizing microarray analysis using and arranging multiple sets of probes for analyzing sequence mutation.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

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During a telephone conversation with Tor Smeland on June 29, 2004, a provisional election was made with traverse to prosecute the invention Group I claims 1-5, 10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-9 and 11-14 are withdrawn from further consideration by the examiner, 37 CFR 1.14(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

2. Claim 1 is objected to because of the following informalities: Lines 12 and 13 of claim 1 contain the typographical errors "adjacent the" and "nucleic probe." Appropriate correction is required.
3. Claim 3 contains the trademark/trade name Starfrost® without the generic description of the slide. Appropriate correction is required. The use of the trademark Starfrost® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murtagh, Jr. et al. (USPN 5,744,306 04/28/1998) in view of Sabanayagam et al. (WO 98/59243 12/30/1998).

Murtagh, Jr. et al. teach to a method for detecting a nucleotide sequence within a double-stranded DNA in a sample comprising coating a solid support with a layer of biotinylated serum albumin. They also teach digesting the double-stranded DNA to convert it to single-stranded DNA, hybridizing the single-stranded DNA with a first nucleic acid probe and one or more second nucleic acid probes labeled with a detectable moiety and can hybridize with the single-stranded DNA adjacent the hybridized first nucleic acid probe, ligating the first and second nucleic acid probes, denaturing the ligated first and second nucleic acid probes from the single-stranded DNA to which they were hybridized, removing labeled probes not covalently bonded to single-stranded DNA and detecting the detectable moiety that is ligated to the first nucleic acid probe indicating the presence of the nucleotide sequence in the double-stranded DNA in the sample (see col. 6 lines 60-67, col. 7 lines 1-11). With regard to claim 5, they teach the detectable moiety on the second nucleic acid probe as digoxigenin and detecting it by binding the digoxigenin with anti-digoxigenin antibody fragments (see col. 32 line 5).

With regard to claims 1, Murtagh, Jr. et al. do not teach an amount to create sufficient binding sites for capture probes, drying and incubating with a second layer of streptavidin having sufficient density to perform microarray analysis. With regard to claim 3, they do not teach the solid glass support as Starfrost glass (glass slide). With regard to claim 4, they do not teach the first nucleic acid probes are placed on the glass support by light-directed oligonucleotide synthesis.

Sabanayagam et al. teach an amount to create sufficient binding sites for capture probes, drying and incubating with a second layer of streptavidin having sufficient density to perform microarray analysis. With regard to claim 3, teach the solid glass support as Starfrost glass (glass slide). With regard to claim 4, they teach the first nucleic acid probes are placed on the glass support by light-directed

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oligonucleotide synthesis (see whole document, specifically p. 7 lines 17-33, p. 8 lines 1-25, p. 11

Example 3).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Sabanayagam's method of placing nucleic acid probes on a glass support with Murtagh's method for detecting a nucleotide sequence within a double-stranded DNA in order to detect a nucleotide sequence within a double-stranded DNA with greater efficiency. Sabanayagam et al. state using light-directed strategies creates a new approach to the manufacture of high-density arrays on biochips because it allows for controlled or patterned placement of molecules (p. 2 under 'Summary of the Invention'). It would have been prima facie obvious to apply Sabanayagam's method of placing nucleic acid probes on a glass support to Murtagh's method for detecting a nucleotide sequence within a double-stranded DNA to achieve the expected advantage of detecting a nucleotide sequence within a double-stranded DNA with greater efficiency.

Summary

6. No claims allowed

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita, Ph.D. whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on weekdays 7:30 A.M. - 4:00 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

hgc


JEFFREY FREDMAN
PRIMARY EXAMINER
